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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/698,496

10/31/2003

Steven L. Jacques

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EXAMINER

NGUYEN, TUAN VAN

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/698,496	Applicant(s) JACQUES, STEVEN L.	
	Examiner TUAN V. NGUYEN	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 22-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-19 and 22-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/7/07, 7/9/07</u> | 6) <input type="checkbox"/> Other: _____ |

DETAIL ACTION

1. In previous Office action, claims 1-29 were pending, claims 1-13 and 25 have been withdrawn from further consideration, and claims 14-29 were examined and rejected.

Response to Amendment

2. According to the Amendment applicant filed on December 07, 2007, claims 30 and 31 are new, claims 20 and 21 have been cancelled. Accordingly, claims 1-19 and 22-31 are pending in this present application and claims 14-19, 22-24 and 26-31 are presented for examination.
3. Examiner acknowledges the 510(k) Summary fails to disclose the tip outer diameter of 4.9 Fr or 0.064 inches. Applicant argument with respect to claim 14 has been fully considered and persuasive, therefore, the rejection is hereby withdrawn. However, claims 14-19, 22-24 and 26-29 are rejected in view of new ground of rejection necessitate by amendment.
4. Declaration Under 37 C.F.R. § 1.132 has been fully considered. However, the assertion that "To a person with endoscopic industry knowledge and experience such as myself, the term "<5" and "sub 5" strongly suggest that Boston Scientific/Microvasive did not have real, measurable outer diameters below 5 French" is not persuasive. The term "<5" and "sub 5" indicate that the outer diameters is below 5 French.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. **Claims 14, 15, 19, 22-24 and 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchins et al. (U.S. 6,676,659) in view of Richardson (U.S. Pub. No. 2003/0078473) further in view of Howell et al (US 6,740,277).**

8. Referring to **claims 14, 15, 23-24 and 26-30**, Hutchins discloses (see Figs. 3, 4, and 6) a papillotomy and sphincterotomy device comprising: a shaft 11 having proximal end and distal end; a distal terminus 14, one lumen for receiving 0.35 inches guide wire; one lumen 17 for cutting wire 37; wherein the cutting wire 37 is exiting a skive hole 36B then entering the second skive hole 36A and the distal tip of cutting wire is anchor by anchoring member 35; the thirds lumen 16; and the

distal tip wherein the distal tip having a diameter measuring 0.07 and the distal tapered tip (see col. 5, line 45 to col. 7, line 14). Hutchins discloses the invention substantially as claimed except for specifically disclosing the length of the taper portion of the tip is approximately 3 mm or less and the distal terminus has an outer diameter less than approximately 0.063 inch.

9. Still referring to **claims 14, 15, 23-24 and 26-30**, however, Richardson discloses a biliary catheter (see Fig. 3) having a tapered distal tip wherein the length of the tapered tip is about 0.10 cm (1 millimeter) to 5.0 cm (50 millimeters) for the purpose increase the probability of initially getting into a smaller opening such as the orifice of Vater (see paragraph [0038]-[0039]). However, Richardson fails to disclose the distal terminus has an outer diameter less than approximately 0.063 inch.
10. Still referring to **claims 14, 15, 23-24 and 26-30**, however, Howell discloses a method of making a tapered tip for a catheter wherein the design intended of the tapered tip is for facilitating the insertion of the catheter into a vessel and to avoid discomfort and tissue trauma to the patient (see col. 1, lines 50-55). Howell also discloses the outer diameter of catheter may have a diameter of 0.020 to 0.140 inches (see col. 5, lines 35-43) and the tapered tip may have a configuration according to US Patent No. 4,588,398 (see col. 4, lines 38-45). Now, turning to US Patent No. 4,588,398 issued to Daugherty et al. Figure 1 of Daugherty's drawings discloses a catheter having a tapered tip configuration that includes the length of the tapered portion and outer diameter of the terminus (see col. 3, line 25 to col. 4,

lines 50). Since it has been held that use of known technique to improve similar devices in the same way and applying a known technique to a known device ready for improvement to yield predictable results are old and well known in the art, therefore, it would have been obvious to one of ordinary skill in the art to use the desired of increase the probability of initially getting into a smaller opening such as the orifice of Vater as suggested by Richardson and teaching of how to make a tapered tip catheter as suggested Howell to modify the tip of Hutchins catheter so that it too would have the same advantage. With respect to the dimensions that that claimed by the applicant, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

11. Referring to **claims 20 and 21**, it has been held that a comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning patentability of the product. In re Fessman, 489 F2d 742, 180 U.S. P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether it is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. In re Klug, 333 F2d 905, 142 U.S.P.Q. 161 (CCPA 1964). In an ex parte case, product-by-process claims are not construed as being limited to the product formed by the specific process recited. In re Hirao et al., 535 F2d 67, 190 U.S.P.Q. 15, see footnote 3.
12. Referring to **claim 31**, Figure 11 of Hutchins's drawings discloses at least two lumens extend to and open to the distal terminus of the catheter.

13. **Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchins et al. in view of Richardson and Howell as applied to claim 13 above and further in view of Sadamasa (U.S. 6,017,339).**
14. Referring to **claims 17 and 18**, the modified device of Richardson discloses the invention substantially as claimed except for the radiopaque marker located at the distal end of the cutting wire and inside the lumen of the cutting wire. Sadamasa discloses an endoscopic diathermic knife (see Fig. 2) for performing endoscopic papillotomy or sphincterotomy (see Background of The Invention) having a radiopaque marker 21 at the distal of the cutting wire 16a and inside the lumen of the cutting wire for the purpose of visually locating the location of the distal tip (see col. 6, lines 18-32). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate the marker to the cutting wire, as disclosed by Sadamasa, to the modified device, as disclosed by Hutchins so that it too would have the same advantage.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V. NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/T. V. N./

Examiner, Art Unit 3731

/(Jackie) Tan-Uyen T. Ho/

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